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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/808,706 | 03/14/2001 | William A. McMillan | 22660-0025 DIV 2 | 6375 |

25225 7590 07/18/2002
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EXAMINER

TAYLOR, JANELLE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808706

Applicant(s)

McMillan et al

Examiner

Taylor, J.

Group Art Unit

1634

---The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address---

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6-7-02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-28 is/are pending in the application.
- Of the above claim(s) 9-28 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-8 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Other Detailed Action

Office Action Summary

DETAILED ACTION

Election/Restrictions

1. Claims 9-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7. The traversal is on the ground(s) that the current application presents the claims originally assigned to group III of the parent application. This is not found persuasive because, upon further review, the claims were deemed to comprise different groups, as outlined in the restriction requirement in paper #6. The groups all have different modes of operation. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood (USPN 5,776,889) in view of Berndt (USPN 6,080, 574).

Atwood teaches a method for determining the characteristics of the concentration growth of target nucleic acid molecules in a PCR reaction sample. Specifically, Atwood teaches "a method of accurately determining the starting concentration of target nucleic acid molecules based on observation of fluorescence during each cycle of the PCR

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process." (Col. 3, lines 21-23). Atwood also teaches "the starting molar concentration of DNA template in the unknown samples is determined by performing the same PCR under the same conditions as for the PCRS on the known standards, and recording the growth curves." (Col. 4, lines 46-49). This is done by "detecting and measuring the intensity of the signal during at least the extension portion of each of the cycles, converting said intensity to molar concentration values for each of the extension portions of each of the cycles, generating a measured curve of molar concentration of dsDNA versus cycle number from the stored concentration values...and providing a best fit of the measured curve and one or more known growth curves." (Abstract). This is done by measuring the fluorescence of the samples during each cycle of the PCR. The data were then fed to a conventional spreadsheet program in the computer for normalization and manipulation of the resulting intensity values for each well. (Col. 1). Also, Figures 1-3 show the growth curves. Atwood also teaches "One method of determining the best fit between the calculated and measured growth curves is to take the difference between the measured and calculated molar concentrations at each cycle measured, square this difference, and sum the square of the difference. Then vary the parameters to be determined to minimize the sum of the squares. *Any method that gives equivalent results will work.*" (Col. 4, lines 58-64).

Although Atwood does teach a mathematical formula for providing a best fit curve, it does not specifically teach a derivative or a second derivative of the growth curve.

Berndt teaches composite optical blood culture sensors, which use fluorescence decay time and fluorescence intensity that depend on a first chemical parameter, such as oxygen concentration. Berndt teaches a derivative of the growth curve for measuring a change in fluorescence. (Col. 4, description of Fig. 14. Also, Fig. 14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the derivative growth curve of Berndt with the teachings of Atwood. Derivatives, both first and second, were well known in the art at the time of the invention and it was well known that they were applicable to a variety of fields. It would have been obvious to use a derivative growth curve to interpret the results of Atwood because derivatives allow the viewer to more easily understand a graph and to pick out the point at which the data diverges, or in the instant case, at the point where the threshold cycle occurs. Furthermore, although neither Atwood nor Berndt teach that the peak occurs at a positive, negative, or zero point, it was well known in the art that derivatives were useful in extrapolating data into a variety of conformations.

Summary

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood in view of Berndt. No claims are free of the prior art.

Conclusion

Any inquiries of a general nature relating to this application, including information on IDS forms, status requests, sequence listings, etc. should be directed to the Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 872-9306 or 872-9307 (after final). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

July 12, 2002



ETHAN C. WHISENANT
PRIMARY EXAMINER